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**UNITED STATES DISTRICT COURT  
 NORTHERN DISTRICT OF CALIFORNIA  
 SAN FRANCISCO DIVISION**

UNITED STATES OF AMERICA; STATES OF  
 CALIFORNIA, COLORADO, CONNECTICUT,  
 DELAWARE, FLORIDA, GEORGIA, HAWAII,  
 ILLINOIS, INDIANA, IOWA, LOUISIANA,  
 MICHIGAN, MINNESOTA, MONTANA,  
 NEVADA, NEW JERSEY, NEW MEXICO, NEW  
 YORK, NORTH CAROLINA, OKLAHOMA,  
 RHODE ISLAND, TENNESSEE, TEXAS,  
 VERMONT, AND WASHINGTON; THE  
 COMMONWEALTHS OF MASSACHUSETTS  
 AND VIRGINIA; AND THE DISTRICT OF  
 COLUMBIA,

*ex rel.* ZACHARY SILBERSHER,

Plaintiffs,

v.

ALLERGAN, INC., ALLERGAN USA, INC.,  
 ALLERGAN SALES, LLC, FOREST  
 LABORATORIES HOLDINGS, LTD., ADAMAS  
 PHARMA, AND ADAMAS  
 PHARMACEUTICALS, INC.,

Defendants.

Case No.: 3:18-cv-03018-JCS

**JOINT CASE MANAGEMENT  
 STATEMENT**

Chief Magistrate Judge Joseph C. Spero

Case Management Conference Date:  
 February 5, 2021

Time: 9:30 a.m.

Place: Courtroom G, 15<sup>th</sup> Floor  
 Phillip Burton Federal Building  
 450 Golden Gate Avenue  
 San Francisco, CA 94102

Action Filed: April 25, 2018

Pursuant to the Court's December 11, 2020 Order, Dkt. 135, Plaintiff-Relator Zachary Silbersher ("Relator"), on behalf of the United States of America and the Plaintiff States; and Defendants Allergan, Inc., Allergan USA, Inc., and Allergan Sales, LLC, and Forest Laboratories Holdings, Ltd. (collectively, "Allergan"); and Adamas Pharma, LLC and Adamas Pharmaceuticals, Inc. (together, "Adamas") ("Allergan" and "Adamas" together, "Defendants") (Defendants with Relator, the "Parties"), jointly file this Case Management Statement.<sup>1</sup>

Pursuant to Fed. R. Civ. P. 26(f), Relator met and conferred with the Defendants on December 28, 2020 and again on January 7, 2021. The Parties now submit this Report pursuant to L. Civ. R. 16-9(a). The Parties were able to reach agreement as to most issues. Any topic areas upon which the Parties were unable to agree are addressed with separate statements from the Parties setting forth their respective positions.

**1. Jurisdiction and Service:**

**Relator's Statement:** As stated in Relator's First Amended Complaint (the "Complaint") (Dkt. 12), the Court has subject matter jurisdiction over the federal claims pursuant to 28 U.S.C. § 1331 and 31 U.S.C. §§ 3730 & 3732. The Court has supplemental subject matter jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367 and 31 U.S.C. § 3732(b). The Court has personal jurisdiction over each of the Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because Defendants can be found in and transact business in this District. Relator has served all Defendants. Defendants have not challenged jurisdiction or venue.

**Defendants' Statement:** The Allergan Defendants waived and/or stipulated to the adequacy of service of process. *See* Dkt. 31 at 2. Defendants do not challenge personal jurisdiction, venue, or subject matter jurisdiction over the federal claims, but challenge subject matter jurisdiction over Relator's state law claims.

<sup>1</sup> Allergan plc was originally named as a defendant but was dismissed pursuant to the stipulation of the Parties and Court order. *See* Dkt. 93.

1 **2. Facts:**

2 **Relator's Statement:** The Complaint alleges that Defendants committed fraud to cause the  
 3 United States and Plaintiff States to pay substantially more for the drugs Namenda XR® (memantine)  
 4 and Namzaric® (memantine and donepezil) than they would have otherwise paid. Specifically, the  
 5 Complaint alleges that Defendants misled the Patent Office into issuing invalid patents protecting  
 6 these drugs. They then submitted the invalid patents to be listed in the FDA's database of "Approved  
 7 Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book."  
 8 Defendants were permitted to submit for listing only valid patents that "could reasonably be asserted"  
 9 against generic competitors. *See* 21 U.S.C. § 355(b)(1). Defendants, however, knowingly submitted  
 10 the fraudulent patents to the government for listing in the Orange Book to block generic competitors'  
 11 entry into the market through drawn-out compulsory patent litigation resulting from the Orange Book  
 12 listings.

13 Defendants' "fraudulent course of conduct" caused government programs to pay too much for  
 14 the drugs, violating the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733; and the false claims act  
 15 of the respective plaintiff States and the District of Columbia. Relator alleges that each and every  
 16 claim for payment for Namenda XR and Namzaric reimbursed by or directly purchased by a  
 17 government agency was a false claim for three reasons. *First*, under promissory fraud, Defendants  
 18 caused claims for payment or reimbursement for Namenda XR and Namzaric to be submitted to the  
 19 government at illegally inflated prices based on an upstream "original" fraud committed by  
 20 Defendants. *Second*, under the implied false certification doctrine, Defendants are liable for  
 21 misleading the government into believing that the prices offered to the market were not tainted by  
 22 fraud but in fact were "fair and reasonable." *Third*, Defendants made factually false claims, because  
 23 the applications for the fraudulent patents were themselves actionable false claims. This is because the  
 24 patents were obtained through Defendants' misrepresentations and misleading omissions during the  
 25 prosecution of the patent. A "claim" under the FCA includes any request for property—and patents  
 26 are property. Thus, the patent applications were false claims, which proximately caused the  
 27 government to suffer significant damages. 31 U.S.C. § 3729(a)(1)(A), (B).

1 The total damages to the government likely exceed \$2 billion, not counting treble damages,  
2 statutory penalties, and statutory award of attorneys' fees.

3 **Allergan's Statement:** The two drugs at issue here are treatments for individuals with  
4 dementia and Alzheimer's disease. The U.S. Food and Drug Administration ("FDA") initially  
5 approved Namenda® in 2003; the version of the drug at issue in this case, Namenda XR®, is an  
6 extended-release version of the drug approved by the FDA in June 2010. Dkt. 12 ¶¶ 50–51. Namzaric®,  
7 which pairs the active ingredient in Namenda XR® with that in another Alzheimer's drug, was initially  
8 approved by the FDA in 2014. *See id.* ¶ 108. The Complaint's two core allegations relate to patents  
9 obtained in 2011 and 2012, when the Adamas Defendants and Forest Labs (one of the Allergan  
10 Defendants), respectively, sought patents for new formulations and delivery methods for Namenda®.

11 Based on public patent prosecution files, as well as other public domain information such as  
12 Securities and Exchange Commission ("SEC") reports and Medicare data, Relator brought this *qui*  
13 *tam* action, advancing a convoluted theory with substantial factual holes. As to one group of patents  
14 (the Went Patents), Relator will be unable to prove *any* conduct by Allergan before the U.S. Patent  
15 and Trademark Office ("PTO"), as Allergan (through Forest Labs) only became involved *after* the  
16 alleged misconduct. Relator alleges in the Complaint that Forest Labs entered into a license agreement  
17 with Adamas in November 2012, *see* Dkt. 12 ¶ 58, *after* the purportedly fraudulent conduct by  
18 Dr. Went and Adamas took place with respect to the patent prosecution, *see id.* ¶¶ 61, 63, 69–80.<sup>2</sup> As  
19 to the remaining patent (the '009 patent), Relator will be unable to prove any facts that support a claim  
20 of knowing misconduct by Forest Labs. He similarly does not plead, and will be unable to prove, any  
21 facts sufficient to show the requisite intent by any Allergan Defendant in making any claims for  
22 payments, or, in fact, any specific representation—express or implied—that was actually false in  
23 connection with such claims.

24 Despite the publicly disclosed information regarding the allegations and transactions  
25 underlying Relator's Complaint, federal and state health care programs continue to pay for  
26 Namenda XR® and Namzaric®. Dkt. 12 ¶¶ 165, 175, 187.

27 \_\_\_\_\_  
28 <sup>2</sup> Allergan recognizes that the Court has accepted these allegations as sufficient at the pleading stage  
(Dkt. 135), but nonetheless contests whether Relator can prevail on a claim based on these facts.

1       **Adamas’ Statement:** Adamas owns the so-called “Went Patents” relating to memantine, an  
 2 active pharmaceutical ingredient in two Alzheimer’s medications—Namenda XR® and Namzaric®—  
 3 that Allergan markets and sells in the United States under an exclusive license from Adamas. Dkt. 12  
 4 ¶¶ 58–59. Allergan started selling Namenda XR in 2013, and Namzaric in 2015.

5       Relator filed this lawsuit in 2018. He is not a traditional FCA “insider” who alerts the  
 6 government to unknown financial fraud. Instead, he is an outsider simultaneously litigating highly  
 7 similar claims against numerous pharmaceutical companies, none of which ever employed him. In  
 8 each case, he has pieced together allegations and transactions from publicly-available documents and  
 9 databases in an effort to state an FCA claim. In the present action, Relator alleges Defendants caused  
 10 various federal health care programs to receive allegedly “false” claims for Namenda XR and  
 11 Namzaric from 2013 to present. Dkt. 12 ¶ 145. But he does not describe any particular reimbursement  
 12 claim for these drugs, let alone identify one containing an expressly false statement or certification.  
 13 Instead, Relator asserts that claims seeking government payment for Namenda XR and Namzaric are  
 14 *impliedly* false because they fail to disclose Defendants’ alleged noncompliance with assorted federal  
 15 regulations. *Id.* ¶¶ 110–120. With respect to Adamas, Relator alleges the company breached its duty  
 16 of candor to the PTO when procuring the Went Patents and, because enforcement of those patents  
 17 “wrongfully” delayed generic competition, Allergan breached a purported obligation to provide “fair  
 18 and reasonable” pricing for Namenda XR and Namzaric on the Federal Supply Schedule (“FSS”). *Id.*  
 19 ¶¶ 57–90, 112–113.

20       Relator’s allegations concerning Adamas are identical to meritless inequitable conduct claims  
 21 that Amneal Pharmaceuticals LLC (“Amneal”) filed in connection with patent infringement litigation  
 22 back in 2014. Adamas disclosed these very same allegations to the United States through Information  
 23 Disclosure Statements (“IDSs”) submitted to the PTO in 2016. Adamas’ IDSs included the Amneal  
 24 inequitable conduct counterclaims as an attachment. Dkt. No. 68-1 is a chart placing Amneal’s  
 25 allegations side-by-side with the facts alleged in Relator’s operative pleading, as well as numerous  
 26 publicly available documents containing all of the essential facts underlying Amneal’s allegations.  
 27 The chart demonstrates starkly that Relator’s allegations “mirror” Amneal’s allegations, without  
 28 adding any original content. *See* Dkt. 135 at 30–31. Every document referenced in Amneal’s

1 allegations and Relator's Complaint has been publicly available to view and download from the PTO's  
 2 Patent Application Information Retrieval website ("Public PAIR") since at least 2013, five years  
 3 before Relator filed this lawsuit.

4 Adamas' IDS reports are available on Public PAIR as well, but their attachments—including  
 5 the Amneal counterclaims—are not. *See* Dkt. 135 at 31 n.11. To obtain certified copies of these  
 6 attachments, a member of the public need only submit a written request to the PTO's Public Records  
 7 Division. *See* PAIR FAQs, available at [https://www.uspto.gov/patents-application-process/checking-](https://www.uspto.gov/patents-application-process/checking-application-status/pair-faqs#)  
 8 [application-status/pair-faqs#](https://www.uspto.gov/patents-application-process/checking-application-status/pair-faqs#). If Relator or any third party submitted a public records request covering  
 9 the attachments to Adamas's IDS reports before Relator filed his Complaint, those attachments were  
 10 likely "publicly disclosed" within the meaning of the FCA's public disclosure bar, 31 U.S.C. §  
 11 3730(e)(4). Adamas intends to explore this issue with Relator and, if necessary, the PTO if and when  
 12 this case proceeds to discovery.

### 13 **3. Legal issues:**

14 **Relator's Statement:** On December 11, 2020, the Court denied Defendants' motions to  
 15 dismiss the Complaint. Dkt. 135. On December 30, 2020, Defendants filed a motion to have the Court  
 16 certify its Order denying its motion to dismiss for interlocutory appeal under 28 U.S.C. § 1292(b) and  
 17 to stay the case pending the resolution of such appeal, or in the alternative, to stay this case pending  
 18 the Ninth Circuit's decisions in *United States ex rel. Silbersher v. Valeant Pharmaceuticals*  
 19 *International, Inc.*, and *United States ex rel. Integra Medical Analytics LLC v. Providence Health &*  
 20 *Services*. Interlocutory appeal is to be "applied sparingly and only in exceptional cases." *In re Cement*  
 21 *Antitrust Litig.*, 673 F.2d 1020, 1027 (9th Cir. 1982). Use of immediate interlocutory appeals is  
 22 reserved for "extraordinary cases," and is "not intended merely to provide review of difficult rulings  
 23 in hard cases." *United States Rubber Co. v. Wright*, 359 F.2d 784, 785 (9th Cir. 1966), Relator believes  
 24 Defendants have failed to meet their burden of establishing that this is an "extraordinary" case that  
 25 warrants interlocutory review, and the Court should accordingly exercise its discretion to deny the  
 26 motion to certify for the reasons to be set forth in Relator's opposition brief.

27 Relator does not believe there are any other legal issues to resolve at this time and intends to  
 28 vigorously prosecute this matter according to the proposed schedule set forth below.

**Defendants’ Statement:** Because Relator’s claims stem from publicly reported information and he is not an original source, the FCA’s public disclosure bar may dispose of his case if the Ninth Circuit were to reverse this Court’s interpretation of the bar’s scope. Accordingly, Defendants have petitioned the Court to certify its Order denying Defendants’ motions to dismiss (Dkt. 135) for interlocutory review under 28 U.S.C. § 1292(b). *See* Defendants’ Notice of Motion and Motion to Certify Order for Immediate Appeal and for Stay; Memorandum of Points and Authorities, Dkt. 136 (“Motion to Certify”).

The questions identified in the Motion to Certify are “controlling question[s] of law as to which there is substantial ground for difference of opinion.” 28 U.S.C. § 1292(b). An immediate appeal could eliminate potential waste and inefficiency by avoiding protracted and expensive, but ultimately unnecessary, litigation, including by narrowing the issues to be addressed in this action, if not resolving the case entirely. Defendants have also asked the Court to exercise its discretion under 28 U.S.C. § 1292(b) to stay this case pending the Ninth Circuit’s resolution of Defendants’ appeal, should this Court agree to certify the Motion to Dismiss Order. Alternatively, even if this Court decides not to certify its Order or the Ninth Circuit decides not to hear an interlocutory appeal, a stay is appropriate pending the Ninth Circuit’s forthcoming decisions in the *Valeant* and *Integra* cases, for the reasons set forth in the Motion to Certify.

**4. Motions:**

Allergan filed a motion to dismiss (Dkt. 63) and request for judicial notice (Dkt. 66) on June 14, 2019. Adamas filed a motion to dismiss (Dkt. 68) and request for judicial notice (Dkt. 70) on June 21, 2019. The Court denied the motions to dismiss on December 11, 2020. Dkt. 135.

Defendants filed their Motion to Certify (Dkt. 136) on December 30, 2020, and briefing will be completed by the end of January 2021.

**5. Amendment of Pleadings:**

Relator does not anticipate a need to amend the pleadings.

**6. Evidence Preservation:**

The Parties have reviewed the Northern District’s Guidelines Relating to the Discovery of Electronically Stored Information (“ESI Guidelines”). The Parties have met and conferred pursuant to



Rule 26(f) to discuss reasonable and proportional steps to preserve relevant evidence. Specifically, Relator inquired whether Defendants were aware of any issues regarding evidence that has either not been preserved or is inaccessible. Defendants stated that they are not aware of any such issues. Defendants stated that they had initiated litigation holds. Relator also confirmed that he is preserving all relevant documents, including all documents and correspondence demonstrating that he has knowledge that is independent of and materially adds to public information regarding the allegations and transactions underlying his claims.

Relator emphasized that, due to the nature of the claims, information dating back several years relating to certain topic areas would need to be preserved, including, without limitation, documents relating to: (a) the underlying patent applications; (b) the studies, data, and other prior art referenced in the patent applications, including, without limitation, the M110 and C106 studies; and (c) internal company documents concerning generic defense and revenue erosion analyses relating to Namenda XR (and its predecessor drug, Namenda IR) and Namzaric.

**7. Disclosures:**

The Parties exchanged Rule 26 initial disclosures on October 18, 2019.

**8. Discovery:**

**Relator's Statement:** Relator served his First Requests for Production of Documents on Defendants on December 6, 2019.

To make the proceedings more efficient, Relator has proposed that Defendants begin a rolling document production beginning March 1, 2021 focusing on those documents previously produced by the parties in prior infringement actions relating to the patents that the Complaint alleges were fraudulently obtained by Defendants. This targeted set of documents is plainly relevant and would not be unduly burdensome to produce. It should therefore be produced without delay.

Relator's proposed rolling production would permit Plaintiff immediately to commence targeted review of relevant documents that have already been produced in prior litigation while permitting the parties additional time to meet and confer on ESI search terms and other matters relating to electronic discovery concerning Relator's remaining document requests.



1 To further the efficient and expeditious resolution of this action pursuant to Fed. R. Civ. P. 1,  
 2 Relator also provided Defendants on December 26, 2020 with draft: (a) Stipulation and [Proposed]  
 3 Order Regarding Discovery of Electronically Stored Information (ESI); (b) Stipulation and [Proposed]  
 4 Order Regarding Expert Discovery Protocols; (c) Stipulation and [Proposed] Order Regarding  
 5 Privilege Protocols; and (d) Stipulation and [Proposed] Protective Order. Relator requested that the  
 6 parties confer in good faith to present the proposed stipulations and proposed orders to the Court on  
 7 or soon after the first CMC.

8 The Parties have engaged in initial discussions regarding the draft stipulations and orders listed  
 9 above and will confer in good faith regarding those documents.

10 Defendants have filed a motion for the Court to certify this case for interlocutory appeal or to  
 11 stay this case. During oral argument on Defendants' motion to dismiss, the Court stated that "If I deny  
 12 the motion, then I'll open discovery and we'll set a schedule and get it all done." (Dkt. 116, at 56, lines  
 13 18-19). Interlocutory appeals are reserved for exceptional cases, and the Ninth Circuit often refuses to  
 14 hear interlocutory appeals even when the District Court certifies its decision. Here, the Court's  
 15 decision and order denying Defendants' motions to dismiss is manifestly correct, and there is no good  
 16 reason to further delay the expeditious progress of this action. Consistent with the requirement under  
 17 Fed. R. Civ. P. 1 for the rules to construed to "secure the just, speedy, and inexpensive determination  
 18 of every action and proceeding," the Court should permit this action to move forward expeditiously  
 19 without further delay.

20 **Defendants' Statement:** As explained in their Motion to Certify, Defendants believe that the  
 21 Court should stay this action (1) pending the Ninth Circuit's resolution of Defendants' appeal, should  
 22 the Court agree to certify its Motion to Dismiss Order as requested in that motion, or alternatively  
 23 (2) pending the Ninth Circuit's forthcoming decisions in *Valeant* and *Integra*. This Court previously  
 24 stayed discovery in this case pending resolution of the motion to dismiss under the public disclosure  
 25 bar. Dkt. 111. The same reasons that warranted a stay of discovery pending resolution of the motion  
 26 to dismiss apply equally now, because resolution of the public disclosure bar issue could obviate the  
 27 need for any discovery in this case whatsoever. This is especially critical because, as discussed further  
 28 below, the Parties are likely to seek significant discovery from multiple agencies of the U.S.

1 government, which declined to intervene in Relator's Complaint almost two years ago. Dkt. 7.

2 **9. Class Actions:**

3 There are no class allegations in this case.

4 **10. Related Cases:**

5 Although these cases are not strictly speaking related, Relator is a plaintiff and relator in two  
6 other unsealed cases against other pharmaceutical manufacturers that Relator alleges also fraudulently  
7 obtained patents to exclude generic competition with respect to two other drugs. *See United States ex*  
8 *rel. Silbersher v. Janssen Biotech, Inc. et al.*, No. 2:19-cv-12107-KM-JBC (D.N.J.) (relating to the  
9 prostate cancer drug Zytiga<sup>®</sup>, and originally filed in this District but since transferred); and *United*  
10 *States ex rel. Silbersher v. Valeant Pharms. Int'l, Inc.*, No. 3:18-cv-01496-JD (N.D. Cal.) (relating to  
11 Apriso<sup>®</sup>, prescribed to treat ulcerative colitis). The *Janssen* case in New Jersey is being coordinated  
12 with five antitrust class actions that were filed soon after the *qui tam* action was unsealed alleging  
13 anticompetitive overcharges to private payors based on the same alleged underlying misconduct  
14 Relator alleges in the *qui tam* complaint, *i.e.*, the unlawful exclusion of generic competitors through  
15 the assertion of a fraudulently-obtained patent.<sup>3</sup> Judge Donato of this District concluded that the public  
16 disclosure bar precluded Relator's suit against Valeant, *see* 445 F. Supp. 3d 393 (N.D. Cal. 2020), and  
17 the appeal is pending before the Ninth Circuit, *see* 9th Cir. No. 20-16176.

18 **11. Relief:**

19 **Relator's Statement:** Relator seeks damages on behalf of the federal government and the  
20 Plaintiff States for overcharges paid for Namenda XR from at least July 2014 through at least February  
21 2018 (with some damages continuing to the present); and Namzaric from July 2015 to the present.  
22 CMS reports that Medicare Part D and Medicaid paid a total of \$3.122 billion from July 2014 to  
23 December 31, 2017 (the last date data is available) for Namenda XR and Namzaric based on over 8.5  
24

25 <sup>3</sup> Five antitrust class actions based on the same transactions underlying the *Janssen qui tam* were filed  
26 soon after *Janssen* was unsealed. Those class actions have all been transferred to the District of New  
27 Jersey. Four of those cases—filed on behalf of the City of Baltimore, Blue Cross / Blue Shield of  
28 Louisiana, and various union health plans—have been consolidated into civil action No. 2:19-cv-  
14146-KM-JBC (D.N.J.). A fifth antitrust action, filed by the Self-Insured Schools of California based  
on the same misconduct alleged in the *Janssen* complaint, is pending as civil action No. 2:19-cv-  
14291-KM-JBC (D.N.J.) and has recently been consolidated with the *Blue Cross* action.

1 million separate claims. These amounts do not include direct purchases of Namenda XR and Namzaric  
 2 through government programs such as the Veterans Health Administration or the Department of  
 3 Defense's TRICARE; or reimbursements from other parts of Medicare, such as Medicare Advantage  
 4 (Part C).

5 Thus, damages for fraudulent claims made to Medicare Part D and Medicaid—excluding  
 6 purchases after January 1, 2018—is approximately \$2.8 billion, before trebling and statutory penalties.  
 7 The FCA also authorizes a civil penalty of not less than \$11,463, or more than \$22,927, for each  
 8 violation of the FCA.

9 **Defendants' Statement:** Defendants contend that Relator is not entitled to any relief. In the  
 10 event of a finding of liability, Defendants assert that damages should be limited to (at most) the claims  
 11 actually and proximately caused by the conduct found to violate the FCA and any associated  
 12 incremental cost to the government (rather than the full cost of the drugs at issue). Similarly, any such  
 13 damages must be reduced to account for the value obtained by the government in reimbursing the  
 14 specific claims for the drugs at issue. Such adjustments must be made before any statutory trebling  
 15 under the FCA and state analogues. Additionally, trebling and per-claim penalties may raise due  
 16 process, Eighth Amendment, and other constitutional considerations. All damages must be established  
 17 based on an appropriate methodology and proof.

18 **12. Settlement and ADR:**

19 During the meet and confer Relator informed Defendants that mediation before a magistrate is  
 20 acceptable, as are the other ADR options offered by the Court. Defendants are agreeable to mediation  
 21 in front of a magistrate, although they believe ADR is premature at this time, and would prefer to  
 22 revisit the issue after the Court has ruled on the Motion to Certify.

23 **13. Consent to Magistrate Judge for All Purposes:**

24 All parties have consented to have Chief Magistrate Judge Spero preside over this action for  
 25 all purposes.

26 **14. Other References:**

27 Inapplicable.  
 28

1 **15. Narrowing of Issues:**

2 The Parties do not believe the issues can be narrowed at this stage.

3 **16. Expedited Trial Procedure:**

4 No Party seeks to proceed under the Court's Expedited Trial Procedure.

5 **17. Scheduling:**

6 **Relator's Statement:** The Parties have met and conferred about a potential pretrial schedule.

7 As set forth below, Relator proposes a schedule that would allow trial to proceed in 18 months.

8 Relator believes that many issues on patent validity have already been litigated and subject to  
9 extensive discovery in prior infringement actions, and therefore any discovery burden on Defendants  
10 is greatly diminished in this case.

11 **Defendants' Statement:** Defendants have moved the Court to certify its Order on Defendants'  
12 respective motions to dismiss under 28 U.S.C. § 1292(b) and stay proceedings pending the Ninth  
13 Circuit's resolution of Defendants' appeal, should the Court agree to certify an interlocutory appeal  
14 and the Ninth Circuit agree to hear that appeal, or alternatively to stay proceedings pending the Ninth  
15 Circuit's forthcoming decisions in *Valeant* and *Integra*. Defendants therefore believe that the schedule  
16 set forth below should commence, if necessary, only upon resolution of those issues. Relator opposes  
17 any stay.

18 Defendants also believe that Relator's proposed schedule is too condensed to facilitate  
19 completion of reasonable discovery and other pretrial proceedings given the factual complexity of the  
20 issues presented by this case. This case will require litigation of factual and legal issues extending across  
21 at least three complex areas of law, as the underlying conduct involves patent issues, while Relator's  
22 claims are based on antitrust and unfair competition concepts and his causes of action arise under the  
23 FCA and related state laws. As pleaded, this case involves events that took place in connection with the  
24 prosecution of 13 patents, and Relator has stated his position that discovery should extend back to  
25 January 1, 2004. Further, as pleaded, this case will require discovery from multiple agencies of  
26 government, including, at a minimum, securing information from the PTO and claims data and other  
27 information from the Centers for Medicare & Medicaid Services and the agencies administering the  
28 Children's Health Insurance Program, the Indian Health Service, the Federal Bureau of Prisons' Health

Services Division, the Veterans Health Administration, the Military Health System, CHAMPUS, TRICARE, and the Coast Guard's Office of Health Services. In Defendants' experience, it will take a significant amount of time to obtain discovery from these government agencies, yet such discovery will be necessary before the Parties can complete all required depositions and expert submissions.

In addition to needing more time for discovery, in light of the enormous complexity of trying an unprecedented case of this nature, Defendants also believe that pretrial deadlines should be scheduled for dates after a decision on the Rule 56 motion for summary judgment. Given the legal issues posed by Relator's novel claims, preparing for trial while the Parties await the Court's ruling on those issues would be inefficient.

Notwithstanding disagreements about whether the case should be stayed, the time period for fact discovery, and other pretrial scheduling questions and deadlines, the Parties have worked together to develop the proposed schedule outlined below, which reflects some areas of common ground resulting from the Parties' discussions while highlighting for the Court where the Parties' positions diverge.

EVENT	RELATOR'S PROPOSAL	DEFENDANTS' PROPOSAL
Case Management Conference	February 5, 2021	
Defendants answer the Complaint	March 4, 2021	45 days following Court's entry of a scheduling order <sup>4</sup>
Parties exchange proposed custodians/search terms	March 1, 2021	45 days following Court's entry of a scheduling order
Parties begin rolling document productions	March 1, 2021	60 days following Court's entry of a scheduling order
Deadline to amend pleadings or to add defendants, claims, or defenses, except upon a showing of good cause	April 19, 2021	

<sup>4</sup> The Parties have stipulated to extend the time for Defendants to answer the Complaint until March 4, 2021. Defendants maintain however, consistent with their pending motion for certification and for stay, ECF 136, that further proceedings in the district court at this juncture—such as pleadings responsive to Relator's 551-paragraph Complaint—may prove to be wasteful and unnecessary. Defendants therefore respectfully ask the Court to postpone the deadline to answer until a reasonable period of time following entry of a scheduling order, should that occur.

EVENT	RELATOR'S PROPOSAL	DEFENDANTS' PROPOSAL
Fact discovery closes, including all fact depositions; all discovery must have been timely served to be answerable by this date	180 days following the date that Defendants' Answers to the Complaint are due (or August 31, 2021)  Deadline for substantial completion of document production: 84 days after defendants begin rolling production (or May 24, 2021)	270 days following the date that Defendants' Answers to the Operative Complaint are due  Defendants disagree that the Court should set a deadline for completion of document production in light of the uncertain number of custodians, search terms, and document volumes
The Parties serve merits expert reports	37 days following the close of fact discovery (or October 7, 2021)	37 days following the close of fact discovery
The Parties serve opposing/rebuttal merits expert reports	30 days following service of merits expert report (or November 8, 2021)	30 days following service of merits expert report
The Parties serve reply merits expert reports	28 days following service of opposing merits expert reports (or December 6, 2021)	28 days following service of opposing merits expert reports
Expert discovery closes	14 days following service of reply merits expert reports (or December 20, 2021)	14 days following service of reply merits expert reports
Deadline for Rule 56 and Daubert motions	30 days following service of reply merits expert reports (or January 5, 2022)	30 days following service of reply merits expert reports
Rule 56 and Daubert oppositions	28 days following deadline for Rule 56 and Daubert motions (or February 2, 2022)	28 days following deadline for Rule 56 and Daubert motions
Rule 56 and Daubert replies	14 days following Rule 56 and Daubert oppositions (or February 16, 2022)	14 days following Rule 56 and Daubert oppositions

EVENT	RELATOR'S PROPOSAL	DEFENDANTS' PROPOSAL
Hearing on Rule 56 and Daubert motions	42-day window starting 21 days following the Rule 56 and Daubert replies (or March 9, 2022 through April 20, 2022)	To be set by Court
Parties exchange Rule 26(a)(3) disclosures and preliminary trial memoranda	35 days following Rule 56 and Daubert replies (or March 23, 2022)	35 days following the Court's ruling on Rule 56 motions
Parties file motions <i>in limine</i>	35 days following Rule 56 and Daubert replies (or March 23, 2022)	35 days following the Court's ruling on Rule 56 motions
Parties file oppositions to motions <i>in limine</i>	10 days following the filing of motions <i>in limine</i> (or April 4, 2022)	10 days following the filing of motions <i>in limine</i>
Parties exchange objections to Rule 26(a)(3) disclosures	7 days following filing of oppositions to motions <i>in limine</i> (or April 11, 2022)	7 days following filing of oppositions to motions <i>in limine</i>
Parties exchange counter-objections to Rule 26(a)(3) disclosures	3 days following exchange of objections to Rule 26(a)(3) disclosures (or April 14, 2022)	3 days following exchange of objections to Rule 26(a)(3) disclosures
Parties file replies to motions <i>in limine</i>	3 days following exchange of objections to Rule 26(a)(3) disclosures (or April 18, 2022)	3 days following exchange of objections to Rule 26(a)(3) disclosures
Attorneys' Conference; all motions <i>in limine</i> must be fully briefed by this date.	4 days following filing of replies to motions <i>in limine</i> (or April 22, 2022)	4 days following filing of replies to motions <i>in limine</i>
Draft of Joint Final Pretrial Order, <i>voir dire</i> , and jury instructions exchanged	21 days following Attorneys' Conference (or May 13, 2022)	21 days following Attorneys' Conference
Joint Final Pretrial Order filed with Court	5 days following Draft of Joint Final Pretrial Order (or May 18, 2022)	5 days following Draft of Joint Final Pretrial Order



EVENT	RELATOR'S PROPOSAL	DEFENDANTS' PROPOSAL
First Final Pretrial Conference (proposed)	2 days following filing of Joint Pretrial Order with Court (or May 20, 2022)	2 days following filing of Joint Pretrial Order with Court
Parties file proposed <i>voir dire</i> , jury instructions, original and two copies of final bound exhibits, revised 26(a)(3)/Final Pretrial Order materials, witness summaries, and Final Trial Memoranda	21 days following First Final Pretrial Conference (or June 10, 2022)	21 days following First Final Pretrial Conference
Second Final Pretrial Conference (proposed)	7 days following filing of proposed <i>voir dire</i> (or June 17, 2022)	7 days following filing of proposed <i>voir dire</i>
Trial	Approx. 30 days after Second Final Pretrial Conference (or July 18, 2022)	Approx. 30 days after Second Final Pretrial Conference

**18. Trial:**

Defendants prefer a bench trial. Relator is amenable to a bench trial but reserves his right to request a jury trial. No other trial-related issues were discussed.

**19. Disclosure of Non-party Interested Entities or Persons:**

The Parties have filed Certifications of Interested Entities or Persons with the Court, and restate their contents as follows:

Relator: None.

Allergan: (1) Allergan Holdco US, Inc. (partial owner of Allergan Sales, LLC); (2) Allergan Holdings, Inc. (partial owner Allergan Sales, LLC).

Adamas: Not applicable.

**20. Professional Conduct:**

The attorneys of record for the Parties have reviewed the Guidelines for Professional Conduct for the Northern District of California.

**21. Other Matters:**

None.

1 Dated: January 8, 2021

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1 Dated: January 8, 2021

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**ATTESTATION OF FILER**

I, Nicomedes Sy Herrera, attest that I have obtained the concurrence Defendants' counsel as to the substance of this **JOINT CASE MANAGEMENT STATEMENT**. Messrs. Royall and Holian have authorized the use of their electronic signatures on this document.

Dated: January 8, 2021

By: /s/ Nicomedes Sy Herrera  
Nicomedes Sy Herrera